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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,601	04/03/2000	BERNARD ABRAMOVICI	IVD994	2604

27546 7590 04/23/2003

SANOFI-SYNTHELABO INC.
9 GREAT VALLEY PARKWAY
P.O. BOX 3026
MALVERN, PA 19355

EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/23/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,601

Applicant(s)

ABRAMOVICI ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 1-22 are pending in this application.

Response to Arguments

Applicant's arguments filed February 6, 2003 have been fully considered but they are not persuasive. The rejection made in paper numbers 8 and 11 over Martin-Algarra et al., Story et al. and the Physicians Desk Reference under 35 U.S.C. §103(a) and 35 U.S.C. §102(b) is maintained and is hereby repeated.

Applicant argues that Story et al is inadequate as a reference. In response, In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Martin-Algarra et al. recognize the problem that amiodarone has regarding erratic and variable absorption and also recites that a small amount of non-ionic hydrophilic surfactant solves the problem. Martin-Algarra et al. teach the absorption rate constants of amiodarone are decreased as the surfactant concentration increased and absorption was unusually fast at lower surfactant concentrations (see abstract).

In response to applicant's argument that an oral formulation is not used because of the "*in situ* rat gut technique" for administration of amiodarone, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant's claims are drawn to a composition. Since amiodarone is mixed with polysorbate 80, a non-ionic hydrophilic surfactant, then it meets the claim.

Applicant asserts that there is no "solid pharmaceutical composition" in Margin-Algarra et al. In response, Martin-Algarra et al. teach that some previously reported conclusions regarding the convenience of designing a more reliable form of amiodarone, containing a suitable dose of surfactant as a solid dispersion is confirmed. Martin-Algarra et al. set forth the best mode contemplated for carrying out his invention. Since the methods for tableting solid formulations are well known, Martin-Algarra et al. are clearly in possession of the invention. (An applicant may also show that an invention is complete by a disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics see Synopsis of Application of Written Description Guidelines, at 60, available at <http://www.uspto.gov/web/patents/guides.htm>).

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Regarding the concentrations, applicant alleges that the concentration disclosed in Martin-Algarra is the concentration of nonionic hydrophobic surfactant relative to the active principal. Clearly, on page 2 section 2.2, the text states that the absorption experiments are carried out using eight polysorbate 80 solutions *containing* amiodarone and Page 5 of the reference (section 4.2) teaches 0.75 mg of amiodarone dissolved in 10 ml of perfusion fluids of which include polysorbate 80, which translates to 7.5% by weight of the active principle in base form.

Regarding the double patenting rejection, applicant asserts that the composition of the '778 patent is drawn to parenteral administration. While the composition of the '778 patent is drawn to parenteral formulations, the claims of the instant application are drawn to oral formulations in a gelatin capsule. It is known that liquid formulations may be placed in a gelatin capsule and administered orally. Regarding the buffer solution, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts and as such, does not exclude the addition of a buffer solution.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

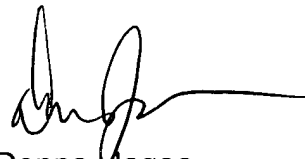
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

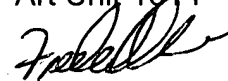
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.




Donna Jagoe
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614



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April 21, 2003